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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/518,471	08/15/2005	Peter Reynolds Foster	9013-67	7924

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EXAMINER

CARRILLO, BIBI SHARIDAN

ART UNIT PAPER NUMBER

1746

DATE MAILED: 08/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/518,471

Applicant(s)

FOSTER ET AL.

Examiner

Sharidan Carrillo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 18 May 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1, 3, 6, 7 and 11-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 6-7, 11-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966); that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1, 3, 6-7 and 11-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Uhlen et al. (6831161) in view of James et al. (US2003/0162225).

Uhlen et al. teach cleaning and sanitizing chromatographic columns by washing

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with 0.1 to 1.0 M NaOH in combination with NaCl for removing prions (col. 2, lines 1-15). Uhlen teaches the invention substantially as claimed with the exception of the concentration of NaCl solution. In paragraph 45, James teaches elution PrP from a chromatography column using 1.5 M NaCl. It would have been obvious to a person of ordinary skill in the art to have modified the NaCl of Uhlen et al., to include 1.15 M NaCl, as taught by James et al., for purposes of eluting PrP (prion protein) from the chromatographic column. Re claim 3, refer to col. 1-2 of Uhlen. Re claim 6, refer to the teachings of James. Re claim 7, it would have been within the level of the skilled artisan to determine what concentration levels of NaCl are needed in order to elute the prions from the chromatography column. Re claim 11, the limitations are met since Uhlen and James teaches a chromatographic column. Re claim 12, Uhlen fails to teach a two-step process of washing with a salt, followed by washing with an alkali. The splitting of one step into two, where the processes are substantially identical or equivalent in terms of function, manner and result, was held not to be patentably distinguishable processes (Ex. Parte Rubin 128 USPQ 159 Po Bd Pat App 1959). Re claim 13, refer to col. 2, lines 10-11 of Uhlen. Re claim 14, Uhlen fails to teach a pH of at least 12. However, it would have been obvious and within the level of the skilled artisan to include a pH of at least 12 since Uhlen teaches an alkaline pH and extreme pH values using NaOH cleaning (col. 2, lines 20-23). Re claim 15, refer to col. 2, lines 14-15. Re claim 16, it would have been within the level of the skilled artisan to have modified the method of Uhlen to include multiple washings, in order to effectively elute the prion from the chromatographic column.

***Response to Arguments***

5. The objection to the disclosure is withdrawn in view of corrections made by applicant.
6. The rejections of the claims, as being anticipated by Prusiner, McDonnell and Gawryl are withdrawn in view of the newly amended claims.
7. The rejection of the claims as being unpatentable over McDonnell is withdrawn in view of the newly amended claims.
8. The rejection of the claims as being unpatentable over Uhlen in view of Gawryl is withdrawn. The Gawryl reference is replaced by the James et al. reference. Applicant argues that Uhlen fails to teach NaCl being used alone. Applicant's arguments are unpersuasive since applicant's claim is open-ended with the term "comprising" to include additional components.
9. In an interview with Ms. Alice Bonnen, on 7/31/2006 the examiner suggested amending the claims to a solution consisting of an aqueous solution of NaCl. However, agreement could not be reached.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Stefas teaches a method of separating prions. However, Stefas has an effective date of 7/2/2002, and applicant's effective date based on the GB English priority document is 6/18/2002. Therefore, Stefas disqualifies as prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharidan Carrillo whose telephone number is 571-272-1297. The examiner can normally be reached on M-W 6:30-4:00pm, alternating Thursday.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Barr can be reached on 571-272-1414. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Sharidan Carrillo  
Primary Examiner  
Art Unit 1746

bsc



SHARIDAN CARRILLO  
PRIMARY EXAMINER